In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 21-0870V

DOMINICK VANORE,	*	Chief Special Master Corcoran
Petitioner,	*	Filed: May 31, 2024
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Ronald Craig Homer, Conway, Homer, P.C., Boston, MA, for Petitioner.

Nina Y. Ren, U.S. Department of Justice, Washington, DC, for Respondent.

ENTITLEMENT DECISION[1]

On February 4, 2021, Dominick Vanore filed a petition for compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program").[2] Petition (ECF No. 1) at 1. Petitioner alleges that an influenza ("flu") vaccine administered to him on October 27, 2018, caused him to experience right-sided sudden sensorineural hearing loss ("SSNHL").

After review of the record, all expert reports and associated literature, I deny entitlement. Many prior reasoned decisions have rejected the general contention that the flu vaccine can cause SSNHL, and the theory presented herein, while slightly different from what I have analyzed in other such cases, fails for comparable reasons. In addition, the timeframe from the date of Petitioner's vaccination to onset of SSNHL was too long to be medically acceptable under the theory presented.

[1] "Under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public in its present form. *Id."*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

I. Factual Background

Petitioner received a flu vaccine on October 27, 2018. Ex. 1 at 7. His prior medical history includes allergies and ear infections, among other things. *See, e.g.*, Ex. 2 at 11, 47; Ex. 4 at 15–16 (documenting a history of ear infections at a 12/17/208 visit); Ex. 8 at 5, 8–14 (reporting a two-to-three-year history of fall allergy symptoms at 12/18/2019 allergy visit); Ex. 14 at 2 (documenting tonsillectomy, adenoidectomy, and tympanostomy tube placement). There is no record evidence of any immediate vaccine reaction.

Petitioner alleges that on November 21, 2018—twenty-five days post-vaccination—he first experienced a sensation of fullness in his right ear when he woke up early that morning. Ex. 14 at ¶ 2 (explaining that it felt as though his ear needed to pop but that the sensation of fullness only continued throughout the day). As noted below, his causation expert has also deemed this to constitute onset in this case—and Petitioner has not proposed an earlier date.

A little more than a week later, on November 29, 2018, Petitioner visited internal medicine specialist Natalie Chen, M.D., at Renown Health, complaining of "right ear 'echoing'," and "fullness," over the prior two weeks. Ex. 11 at 2, 6. He specifically described feeling "stuffy on the right side of the sinus and fullness on [the] right side of the head and right side of the ear," and speculated he was experiencing "airplane ear," since he often traveled by air for work. *Id.* at 6. Dr. Chen's exam revealed that Petitioner's tympanic membrane was "pearly gray." *Id.* at 7. She diagnosed him with eustachian tube dysfunction and instructed him to rinse his sinuses and use antihistamines to alleviate his congestion. *Id.*

That December, Petitioner saw otolaryngologist Jeremy Lough, M.D. Ex. 4 at 7. Petitioner informed Dr. Lough that he had experienced "a little bit of a cold or an allergy flare just a few weeks before" his right ear symptoms began. *Id.* An audiogram performed at this time revealed "asymmetric sensory hearing with [Petitioner's] right being worse than his left in the mid and high frequencies," although he also had normal ability to hear speech and normal ear pressure. *Id.* Petitioner had normal speech discrimination and normal middle ear pressure on both sides. *Id.* Dr. Lough diagnosed Petitioner with SSNHL, prescribed oral steroids and ordered an MRI (which when performed produced normal findings). *Id.* at 6–7; Ex. 11 at 27.

In January 2019, Petitioner returned to Renown Health, where his diagnosis of SSNHL "from virus" was noted. Ex. 2 at 92. He also recounted at this time, however, that he had received "a flu shot several weeks before along with acute URI." *Id.* And he noted that Dr. Lough had surmised that any of the foregoing (even including other previously-resolved infections) could have contributed to his condition. *Id.*

Later that same month, Petitioner was evaluated by another otolaryngologist, Stacey Hudson, M.D., Ex. 5 at 5. He now indicated that "he was having some allergy issues before [his]

hearing loss" incident in November, and that he had experienced "[e]ar problems or surgeries [to his] ear tubes as a child." *Id.* On exam, Dr. Hudson deemed Petitioner's ears to be normal, with clear auditory canals, and intact and clear tympanic membranes. *Id.* She concurred in the diagnosis of sudden idiopathic hearing loss in Petitioner's right ear, recommended further testing, and prescribed oral steroids and an antiviral medication. *Id.* at 6.

Petitioner thereafter continued to seek treatment for his hearing loss issues for the following year, albeit sporadically. Ex. 2 at 107; Ex. 4 at 5–7; Ex. 5 at 2. At such visits, he often noted that a number of possible causes existed for his hearing loss, from vaccination to allergies or even stress. *See, e.g.*, Ex. 6 at 3 (documenting various possible causes at a 2/1/2019 audiology visit). The record from a December 2019 visit with allergist Jeffrey Nugent reveals that the focus was mainly on possible allergens and the impact of allergy-derived rhinitis on the ear canal. Ex. 8 at 4–6. However, Dr. Nugent also took note of Petitioner's recollection that he had "experienced deafness in his right ear [] [two] weeks following [an] influenza vaccination," and stated in response that "[w]ith this being considered a likely neurological adverse side effect, he will not be receiving influenza vaccines in the future." *Id.* at 6.

II. Expert Reports

A. *Petitioner's Expert — Edwin M. Monsell, M.D., Ph.D.*

Dr. Monsell, an otolaryngologist, submitted two written reports on behalf of Petitioner. Report, dated May 19, 2022, filed as Ex. 20 (ECF No. 30-1) ("Monsell First Rep."); Report, dated June 2, 2023, filed as Ex. 95 (ECF No. 46-1) ("Monsell Supp. Rep."). Dr. Monsell opined that the flu vaccine can cause SSNHL.

Dr. Monsell attended Williams College for his undergraduate degree in Biology. *See* Curriculum Vitae, filed as Ex. 21 (ECF No. 30-2) ("Monsell CV"). Thereafter, he attended Duke University for his doctorate in Cell Biology and Neuroscience, and then the University of North Caroline School of Medicine for his medical degree. Monsell CV at 1. For over 20 years, Dr. Monsell has served as a Director and Professor Emeritus of Otolaryngology—Head and Neck Surgery at Wayne State University School of Medicine. *Id.*; First Monsell Rep. at 1. He has maintained an active practice in otology and neurology for over 30 years, treated thousands of patients with hearing loss, and performed over 3,500 major ear operations to remove tumors, infection, and restore hearing. First Monsell Rep. at 1. Dr. Monsell is board certified by the American Board of Otolaryngology—Head and Neck Surgery and holds a Certificate of Added Qualifications from the same board in Neurotology. *Id.*; Monsell CV at 1. In addition, he has published literature specifically on vestibular schwannoma and has around 85 peer-reviewed papers, case reports, and book chapters. Monsell CV at 12–18.

First Report

Dr. Monsell began his first report with a summary review of Petitioner's medical history. Monsell First Rep. at 2–7. He then opined on Petitioner's diagnosis, explaining that on presentation, Petitioner exhibited right ear fullness with an echo-like sound quality in his right ear, leading his treating physicians to initially consider a diagnosis of eustachian tube dysfunction. *Id.* at 7. However, Dr. Monsell maintains that over time and due to the serious nature of Petitioner's condition, the more appropriate diagnosis for Petitioner was SSNHL. *Id.* Petitioner has and continues to have functional and emotional consequences causally related to his SSNHL, including unilateral high-frequency hearing impairment, tinnitus, hyperacusis, vestibular symptoms, possible cochlear implantation surgery, and possible cognitive consequences, plus functional deficiencies that would inherently be emotionally debilitating. *Id.* at 7–10.

Dr. Monsell next attempted to discount several potential alternative explanations for Petitioner's sudden hearing loss. Monsell First Rep. at 11. For example, he doubted that eustachian tube dysfunction[3] was explanatory, opining that patients with SSNHL who present to their primary care physicians are oftentimes misdiagnosed due to the symptoms and signs of one-ear fullness, but without taking into account impaction of ear wax (a hallmark of eustachian tube dysfunction). *Id.* Indeed, "[t]he sensation of ear fullness that is often associated with SSNHL is usually indistinguishable from the sensation of fullness that can occur when the pressure of air in the middle of the ear has not returned to normal immediately after air travel." *Id.* Dr. Monsell also admitted that Petitioner traveled frequently for business and suffered from nasal allergies, but he maintained that Petitioner's experienced sensation of ear pressure (which he opined was consistent with SSNHL) was likely neuropathic in nature, and thus could not be attributed to a physical issue or barometric pressure associated with air travel. *Id.* at 12. Moreover, Dr. Monsell noted that an echo-like sensation is consistent with a diagnosis of SSNHL, but that when the hearing loss presents as relatively mild, it can lead to a misdiagnosis. *Id.*; A. Shuman et al., *Tuning Fork Testing in Sudden Sensorineural Hearing Loss*, 22 JAMA Intern. Med. 706 (2013), filed as Ex. 81 (ECF No. 38-10).

Another possible explanation, Noise-Induced Hearing Loss ("NIHL") and age-related sensorineural hearing loss, while the most common forms of hearing loss, were not deemed reasonable by Dr. Monsell given the facts. Monsell First Rep. at 13. NIHL develops gradually and affects both ears, unlike Petitioner's presentation in the instant case. In addition, NIHL is typically associated with hearing levels at 4 kHz, which was also not documented in Petitioner's medical records. Similarly, "[c]ross-sectional and longitudinal epidemiologic studies show that humans

[3] "Eustachian Tube Dysfunction (ETD)" is defined as the failure of the eustachian tube in maintaining pressure equalization or mucociliary transport. This is categorized as either acute (less than 3 months presentation) or chronic ETD (more than 3 months). . . ." *Eustachian Tube Dysfunction*, National Library of Medicine, https://www.ncbi.nlm.nih.gov/books/NBK555908/ (last visited May 31, 2024).

gradually lose hearing in both ears as we age—with age-related hearing loss generally present by the 60s." *Id.* But Petitioner was only thirty-eight at the time of vaccination, and thus not old enough to show signs of early-onset age-related hearing loss. *Id.*; Ex. 16 at 6.

Dr. Monsell also excluded Meniere's disease[4] as explanatory. Monsell First Rep. at 13. Meniere's disease presents with low-frequency and fluctuating sensorineural hearing loss. *Id.* Based on the filed medical records, however, Petitioner had experienced *high-frequency* sensorineural hearing loss, and his levels did not demonstrate improvement at any time. *Id.* at 13–14; Ex. 4 at 9, 10, 12–13; Ex. 6 at 3. And Petitioner's symptoms of dizziness were non-specific and otherwise not consistent with Meniere's. Monsell First Rep. at 14–15; B. Pearson & D. Brackmann, *Committee on Hearing and Equilibrium Guidelines for Reporting Treatment Results in Meniere's Disease*, 93 Otolaryngol. Head Neck Surg. 579 (1985), filed as Ex. 34 (ECF No. 33-3); Ex. 4 at 5–19; Ex. 5 at 2–8.

An infectious process was also not likely the cause of Petitioner's SSNHL, Dr. Monsell proposed. Monsell Rep. at 17. SSNHL is well documented in association with a variety of infections—measles, mumps, some herpetic infections in clinically active cases, and instances of live attenuated virus exposure. *Id.*; S. Merchant et al., *Pathology and Pathophysiology of Idiopathic Sudden Sensorineural Hearing Loss*, 26 Otology & Neurotology 151 (2005), filed as Ex. 58 (ECF No. 35-7) ("Merchant"); M. McKenna, *Measles, Mumps, and Sensorineural Hearing Loss*, 830 Ann. N.Y. Acad. Sci. 291 (1997), filed as Ex. 57 (ECF No. 35-6) ("McKenna"); T. Hulbert et al., *Bilateral Hearing Loss after Measles and Rubella Vaccination in an Adult*, 325 N. Eng. J. Med. 134 (1991), filed as Ex. 48 (ECF No. 34-7). But "[t]he characteristic postmortem finding in experimental viral inner ear infection (laboratory animals) is infiltration of the inner ear with acute and chronic inflammatory cells," and the same had been seen for measles infection in postmortem human temporal bone studies. Monsell First Rep. at 17. Here, there was no such comparable evidence. *Id.* at 17, 18.

Dr. Monsell then opined as to a proposed mechanism for how a flu vaccine could trigger SSNHL, setting forth a seven-step process. Monsell First Rep. at 18. Particularly relevant to this case was Dr. Monsell's contention that the vaccine could stimulate an Acute Phase Reaction ("APR"), noting authority for the hypothesis that "[u]pon vaccination and introduction of antigens into the body, macrophages and dendritic cells are stimulated, producing inflammatory cytokines and triggering APR synthesis in hepatocytes, which function nonspecifically as part of the innate immune system detecting pathogens or vaccination components." R. Khalil & N. Al-Humadi, *Types of Acute Phase Reactants and Their Importance in Vaccination*, 12 Biomed. Rep. 143 (2020), filed as Ex. 49 (ECF No. 34-9) ("Khalil"); *see also* L. Rogers et al., *Microarray Gene*

[4] "Meniere Disease" is defined as "hearing loss, tinnitus, and vertigo resulting from nonsuppurative disease of the labyrinth with edema." *Meniere Disease*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=70588 (last visited May 31, 2024).

Expression Dataset Reanalysis Reveals Variability in Influenza Infection and Vaccination, 10 Front Immunol. (2019), filed as Ex. 75 (ECF No. 38-4) (finding 334 genes coding for inflammatory processes that were expressed in common between flu infection and vaccination, and 644 unique to flu vaccination).

The APR phase could then reduce cochlear blood flow and cause vascular damage, leading to the breakdown of the cochlear blood-fluid barrier. Monsell First Rep. at 21. Fibrinogen, a large molecular-weight glycoprotein and the chief determinate of blood viscosity, is released in response to vaccination, causing an increase in an individual's blood viscosity. *Id.*; C. Rudack et al., *Vascular Risk Factors in Sudden Hearing Loss*, 95 Thromb. Haemost. 454, 458 (2006), filed as Ex. 76 (ECF No. 38-5) (finding that serum fibrinogen levels were significantly higher in patients with SSNHL than in age- and sex- matched controls). Another article involving an animal model examined cochlear blood flow and hearing levels following an intravenous injection of fibrinogen, finding the presence of reduced cochlear blood flow and worsened hearing levels. Monsell Rep. at 21; B. Weiss et al., *Drug-induced Defibrinogenation as New Treatment Approach of Acute Hearing Loss in an Animal Model for Inner Ear Vascular Impairment*, 38 Otology & Neurotology 648, 650–51 (2017), filed as Ex. 90 (ECF No. 39-9).

This reduction of cochlear blood flow, Dr. Monsell proposed, would then lead to cochlear ischemia, which eventually results in injury/reperfusion and generation of reactive oxygen species ("ROS"), creating oxidative stress in cochlear hair cells. Monsell First Rep. at 21; *see also* M. Brown et al., *Cochlear Inner Hair Cells: Effects of Transient Asphyxia on Intracellular Potentials*, 9 Hear Res. 131 (1983), filed as Ex. 33 (ECF No. 33-2) (demonstrating that brief periods of asphyxia caused hyperpolarization of the resting membrane potential and receptor potentials in inner hair cells); H. Randolf et al., *Cochlear Blood Flow following Temporary Occlusion of the Cerebellar Arteries*, 247 Eur Arch Otorhinolaryngol. 226 (1990), filed as Ex. 74 (ECF No. 38-3); Merchant at 158 (suggesting that the most comprehensive histopathologic study of human temporal bones in patients with SSNHL illustrate that the primary cells affected are the inner and outer hair cells and supporting cells).

Thereafter, cochlear hair cells and ROS-capture mechanisms struggle with oxidative stress, and in order to mitigate widespread damage, the caspase pathways become activated. Monsell First Rep. at 22–23. Activation of the caspase pathways leads to apoptosis, programmed death of hair cells, and irreversible SSNHL. *Id.*; *see also* J. Adams, *Clinical Implications of Inflammatory Cytokines in the Cochlea*, 23 Otol Neurotol. 316 (2002), filed as Ex. 22 (ECF No. 32-1). (Dr. Monsell provided more detail as to the proposed mechanism, but it involves subsequent steps in the process leading to hearing loss distant from the proposed initial vaccination trigger, and therefore further description of his theory will not help resolve the matter).

Dr. Monsell then attempted to show how his proposed mechanism fit the facts of Petitioner's case. Monsell First Rep. at 26. Petitioner had experienced a typical and unremarkable onset of SSNHL that began a few weeks post-vaccination—well within the period of maximal activity of the APR after vaccination, he opined. *Id.* Petitioner's demonstrated high-frequency hearing loss "suggests a mechanism that affects mostly the hair cells," and "less likely that he [suffered] significant thrombosis in his cochlear microcirculation; otherwise, his SSNHL may have been worse in the low and middle frequencies." *Id.* Dr. Monsell further maintained that the onset timing of Petitioner's SSNHL was consistent with his proposed mechanism, and within the medically acceptable timeframe accepted in another item of literature. *Id.* at 27; R. Baxter, *Sudden-Onset Sensorineural Hearing Loss after Immunization: A Case-Centered Analysis*, 155 Otolaryngol. Head Neck Surg. 81 (2016), filed as Ex. 29 (ECF No. 32-8) ("Baxter") (observing a non-statistically significant, but meaningful, number of cases of SSNHL 1-14 days following vaccination).[5] In fact, the Institute of Medicine has accepted an immune-mediated response post-vaccination up to 42 days after vaccination (albeit in the context of a wholly-distinguishable injury), suggesting a three-week onset was still medically acceptable, even though outside the timeframe for highest risk set forth in Baxter. Monsell First Rep. at 27; *Adverse Events Associated with Childhood Vaccines* 44–47 (K. Stratton, et al., eds., 1994), filed as Ex. 82 (ECF No. 39-1) (discussing the expected latency between an antecedent event and the first symptoms of GBS as mainly between 7 and 21 days, but occasionally can appear to have latencies between 22 and 42 days).

Importantly, Baxter is not nearly as supportive of causation as Dr. Monsell suggests. Baxter's authors specifically sought to evaluate the risk of sudden sensorineural hearing loss after the receipt of a large number (several million) of commonly-administered vaccines—including the flu vaccine. Baxter at 82–83. Baxter concluded there was no greater risk for hearing loss in the studied subset of patients who received the flu vaccine when compared to background rates. *Id.* at 83. Indeed, even in the risk interval that Dr. Monsell highlights (1-14 days), Baxter found the number of cases of SSNHL observed not to be statistically significant. *Id.*

Supplemental Report

In his supplemental report, Dr. Monsell provided additional background on the complex structure of the inner ear as well as the SSNHL diagnosis. Monsell Supp. Rep. at 1. Dr. Monsell then noted that a person's immune response, and the toxicity of a given vaccination, could vary significantly, especially in light of individual polymorphisms in immune response genes. Monsell Supp. Rep. at 4–5; C. Thomas & M. Moridani, *Interindividual Variations in the Efficacy and Toxicity of Vaccines*, 278 Toxicology 204 (2010), filed as Ex. 85 (ECF No. 39-4). Thus, Dr.

[5] Dr. Monsell's report asserts that Baxter observed 95 cases of SSNHL within 14 days of vaccination. Monsell First Rep. at 27. In fact, Baxter observed only 92 for this defined risk interval. Baxter at 84 (Table 2).

Monsell argued that it is quite possible that individual, rare adverse reactions can occur following vaccination, despite the safe nature of vaccines generally. Monsell Supp. Rep. at 4–5.

Regarding potential alternative causes, Dr. Monsell reiterated his prior discussion on why a variety of infectious causes were inapplicable in this case. Monsell Supp. Rep. at 5. Although Respondent's experts had also proposed an asymptomatic activation of Herpes Simplex Virus (HSV) types 1 and 2 as potentially causal, Petitioner had exhibited no symptoms of viral syndrome, such as fever or body aches, or any other manifestations of active herpes for that matter. *Id.* at 6. And, Dr. Monsell opined, even if Petitioner had tested positive for an HSV infection, it could not be determined that this would explain Petitioner's SSNHL. *Id.*

Eustachian tube dysfunction was also not likely an explanation for Petitioner's hearing loss, in Dr. Monsell's estimation. This diagnosis can often be reliably ruled out when there is no evidence of tympanic membrane retraction or atelectasis, and middle ear pressure by tympanometry is normal. Monsell Supp. Rep. at 6–7. But Petitioner had normal tympanometry each time he was tested in 2018. Moreover, "[n]egative pressure by tympanometry on one given day does not consistently relate to significant middle ear pathology," and "[n]egative middle ear pressure alone cannot be assumed to be a risk for SNHL." *Id.* at 7. Ultimately, because record evidence did not establish that Petitioner had suffered from negative middle ear pressure at the time of his vaccination, evidence or scientific literature in support of this explanation was irrelevant. *Id.*

Dr. Monsell also briefly attempted to rebut the contention that acute/chronic rhinosinusitis with nasal polyps or allergic rhinitis could have caused Petitioner's SSNHL. Monsell Supp. Rep. at 8. Although such an association has not actively been investigated, Dr. Monsell acknowledged the existence of some literature supporting this as a causal explanation. *Id.*; S. Hung et al., *Sudden Sensorineural Hearing Loss is Associated with Chronic Rhinosinusitis: Population-Based Study*, 130 J. Laryngology & Otology 521, 523 (2016), filed as Ex. 102 (ECF No. 46-8) (finding that sudden SNHL was associated with chronic rhinosinusitis in patients of a younger age (less than 60 years), although most cases of sudden SNHL remain idiopathic). But Dr. Monsell felt that Hung contained numerous uncertainties and methodologic limitation. And in any event, the medical record did not firmly support the conclusion that Petitioner had suffered from chronic inflammatory rhinosinusitis, mild allergic rhinitis with predominant vasomotor rhinitis, or seasonal colds—reducing the significance of this particular counter-explanation. Monsell Supp. Rep. at 8.

Finally, Dr. Monsell offered some additional scientific literature to further bulwark his opinion on the timing of Petitioner's symptoms. Monsell Supp. Rep. at 8. One such article had noted that "[a]bnormalities in arterial function and [low-density liproprotein ("LDL")] oxidation may persist for at least 2 weeks after a slight inflammatory reaction induced by influenza vaccination." P. Liuba et al., *Residual Adverse Changes in Arterial Endothelial Function and LDL*

Oxidation after a Mild Systemic Inflammation Induced by Influenza Vaccination, 39 Ann Med. 392, 392 (2007), filed as Ex. 53 (ECF No. 35-2) ("Liuba"). This could explain the latency in Petitioner's case from vaccination trigger to SSNHL. Monsell Supp. Rep. at 8. However, although Liuba does demonstrate a slight elevation in inflammatory biomarkers two days-post vaccination, such elevation was completely resolved at fourteen days (a shorter timeframe than what is at issue in this case). Liuba at 392.

Another article, Dr. Monsell maintained, demonstrated that therapeutic processes to remove fibrinogen and LDL from circulation have proven successful in treatment of SSNHL after steroid therapy has failed, and that "[t]he window for good therapeutic success is approximately 6 weeks," which according to Dr. Monsell, suggests that the processes of SSNHL are still active for at least six week post-onset of symptoms. Monsell Supp. Rep. at 8–9; F. Heigl et al., *Fibrinogen/LDL Apheresis as Successful Second-line Treatment of Sudden hearing Loss: A Retrospective Study on 217 Patients*. 29 Atheroscler Suppl. 95, 100 (2009), filed as Ex. 101 (ECF NO. 46-7) (suggesting that "[c]omplete remissions decrease from 32% within 14 days to 15% within 42 days"). Of course, Heigl's observation of what constitutes an effective treatment window cannot be equated with a post-vaccination-triggering onset timeframe—the two are not the same thing.

B. *Respondent's Expert — Herman F. Staats, Ph.D.*

Dr. Staats, a pathologist/immunologist, offered one written report on behalf of Respondent. Report, dated Oct. 27, 2022 (ECF No. 43-1), filed as Ex. A ("Staats Rep."). Dr. Staats proposed that the flu vaccine could not have caused Petitioner's hearing loss. Staats Rep. at 7.

Dr. Staats attended Salisbury University for his undergraduate degree, and the University of South Alabama for his Ph.D. in Microbiology and Immunology. Curriculum Vitae, filed as Ex. B (ECF No. 43-12) ("Staats CV") at 1. He has held nine different professorships in immunology and pathology since 1996—all at Duke University Medical Center ("DUMC"). Staats CV at 1. He currently serves as Professor of Pathology, Associate Professor of Immunology, and Associate Professor of Medicine at DUMC. *Id.* Dr. Staats leads a research laboratory which focuses on the development and use of vaccine adjuvants, as well as performs research in the area of innate and adaptive immune responses induced by vaccines. Staats Rep. at 1. Dt. Staats also has published numerous peer-reviewed articles discussing the same topics. *Id.* He is certified as a medical technologist by the American Society of Clinical Pathologies. Staats CV as 2.

Dr. Staats summarized the pertinent medical facts before addressing Dr. Monsell's proposed theory and providing his own opinion in the matter. Staats Rep. at 2. He first explained that although flu vaccines are generally expected to induce some local symptoms and/or systemic symptoms associated with inflammation, Petitioner's medical records did not establish that he

suffered any systemic inflammatory response prior to his sudden hearing loss—let alone an inflammatory process occurring "distant from the site of immunization." *Id.* at 3, 4.

In support, Dr. Staats referenced one item of literature discussing the detection of pro-inflammatory cytokines in the blood of individuals following receipt of the trivalent inactivated influenza vaccine and the correlation of vaccine-induced adverse reactions with serum cytokine levels. Staats Rep. at 4–5; L. Christian et al., *Proinflammatory Cytokine Responses Correspond with Subjective Side Effects after Influenza Virus Vaccination*, 33 Vaccine 3360, 3360 (2015), filed as Ex. A-2 (ECF No. 43-3) ("Christian"). Christian had determined that (based on a sample of 56 women, 18 – 40 years in age) vaccinee complaints of injection site soreness were associated with "greater increases in serum TNF-α and MIF in the days following vaccination compared to those with no or mild soreness," thus supporting the conclusion that a localized inflammatory response might become more systemic in some manner. Christian at 3364. But the medical record in this case did not show that Petitioner had suffered any kind of adverse reaction one to two days post-vaccination, reducing the likelihood that he had experienced something more systemic leading to his hearing loss symptoms three weeks later. Staats Rep. at 5.

Equally unlikely, Dr. Staats opined, was the possibility of damaging, ear-specific inflammation simply due to a systemic process activated after vaccination in an upper limb. In so maintaining, Dr. Staats questioned whether Dr. Monsell had provided sufficient literature support for the proposition. Staats Rep. at 5; J. Adams et al., *Selective Activation of Nuclear Factor Kappa B in the Cochlea by Sensory and Inflammatory Stress*, 160 Neuroscience 530, 532 (2009), filed as Ex. 23 (ECF No. 32-2). Adams's authors had aimed to "induce systemic stress" by injecting mice "with LPS"—a lipopolysaccharide that is the "product of bacteria that induces a potent inflammatory response by activation of specific receptors of the innate immune system," and thus an experimental artifact distinguishable in effect from an unadjuvanted, inactivated flu vaccine. Staats Rep. at 5. Moreover, the LPS was injected intraperitoneally, as opposed to intramuscularly, since the former pathway would heighten the speed and intensity of the immunologic reaction. *Id.*

This made it entirely "impossible to compare LPS-induced inflammation and subsequent inner ear inflammation [] to the type of inflammation induced by intramuscular injection of inactivated influenza vaccines." Staats Rep. at 5; *see also* A. Radin et al., *Using the Influenza Vaccine as a Mild, Exogenous Inflammatory Challenge: When does Inflammation Peak?*, 13 Brain, Behavior, & Immunity – Health 1 (2021), filed as Ex. A-4 (ECF No. 43-5) (finding that "[u]nlike endotoxin administration, which results in 100-fold increases in circulating proinflammatory cytokines, influenza . . . vaccines lead to increase in circulating cytokines in the range of 1pg/ml"); J. Valensi et al., *Systemic Cytokine Profiles in BALB/c Mice Immunized with Trivalent Influenza Vaccine Containing MF59 Oil Emulsion and other Advanced Adjuvants*, 153 J. Immunol. 4029 (1994), filed as Ex. A-5 (ECF No. 43-6) ("Valensi") (studying the magnitude of innate immune system activation by LPS compared to activation by influenza vaccines in mice). The data gathered

in Valensi, according to Dr. Staats, likely demonstrated that an inflammatory response induced by LPS is significantly more severe than one induced by vaccination, even when LPS is injected intramuscularly. Staats Rep. at 6.

Dr. Staats also criticized Dr. Monsell's contention that Petitioner's receipt of the flu vaccine caused an APR resulting in the release of proteins capable of reducing cochlear blood flow and subsequently leading to vascular damage to his ear. Staats Rep. at 3. The studies relied upon by Dr. Monsell for this contention had failed to discuss APR "as it relates to vaccine-induced inflammatory responses and systemic adverse events." *Id.* Khalil, for example, actually revealed that "vaccine-induced APR 'usually stabilize[s] quickly, after recovering from a disruption to homeostasis within a few days to weeks; however, APPs expression levels often remain elevated in *long lasting infection*.'" *Id.*; Khalil at 143. (emphasis added). Khalil thus only stood for the unalarming proposition that the flu vaccine triggers "a mild inflammatory response that would not be expected to induce a prolonged systemic inflammatory response and systemic adverse events." Staats Rep. at 3.

Other studies or articles, Dr. Staats maintained, further reduced the reliability of Dr. Monsell's APR-based theory. One article, for example, demonstrated that "active infections resulted in a higher activation of the APR system than the mild activation of the APR system by the influenza vaccine." Staats Rep. at 3; T. McDade et al., *C-Reactive Protein Response to Influenza Vaccination as a Model of Mild Inflammatory Stimulation in the Philippines*, 33 Vaccine 2004, 2006 (2015), filed as Ex. A-9 (ECF No. 43-10) ("McDade"). The McDade study demonstrated a lesser post-vaccination increase in certain biomarkers for inflammation compared to vaccinated individuals with symptoms of active infection. Other articles similarly noted the higher activations due to infection, although not in direct comparison to vaccination. *See, e.g.*, E. Katainen et al., *Local and Systemic Proteolytic Responses in Chronic Rhinosinusitis with Nasal Polyposis and Asthma*, 5 Int Forum Allergy Rhinol. 294 (2015), filed as Ex. A-10 (ECF No. 43-11) ("Katarinen") (reporting median CRP levels of 2.8 mg/l in subjects with chronic rhinosinusitis with nasal polyposis and asthma compared to 0.5 mg/l in healthy controls). Thus, active infections or chronic conditions were simply more likely to "fit" Dr. Monsell's theory than the more limited impact of vaccination. Staats Rep. at 4.

Dr. Staats's report concluded with consideration of the 25-day post-vaccination timeframe for onset of Petitioner's sudden hearing problems, opining that it did not "fit [Dr. Monsell's] proposed mechanism of hearing loss." Staats Rep. at 6. Dr. Staats maintained that "influenza vaccine-induced inflammation is mild and of short duration," as seen in the mice studies. *Id.*; Valensi at 4032 (showing influenza vaccine-induced elevations in cytokine production returned to baseline by 24 hours post-vaccination). Here however, Petitioner's hearing problems occurred more than three weeks post-vaccination. It was unlikely that the one-time impact of a flu vaccine

could have caused sufficient inflammation to produce sudden hearing loss so long after vaccination.

C. *Respondent's Expert — Bryan Ward, M.D.*

Dr. Ward, an otolaryngologist, offered one written report on behalf of Respondent. Report, dated Oct. 31, 2022, filed as Ex. C (ECF No. 43-13) ("Ward Rep."). Dr. Ward concurred with Dr. Staats that Petitioner's sudden sensorineural hearing loss was not likely caused by his prior receipt of the flu vaccine. Ward Rep. at 8.

Dr. Ward attended Haverford College for his undergraduate degree, and the University of Pittsburg School of Medicine for his medical degree. Curriculum Vitae, filed as Ex. D (ECF No. 43-22) ("Ward CV") at 1. He then completed an internship in General Surgery, followed by a residency in Otolarynology-Head & Neck Surgery at Johns Hopkins Hospital. Ward CV at 1. Thereafter, he completed a fellowship in Otology & Eustachian Tub Procedures at Boston Children's Hospital, and another in Neurology & Skull Base Surgery at Johns Hopkins Hospital. *Id.* He is currently an Associate Professor of Otolaryngology-Head and Neck Surgery at Johns Hopkins University School of Medicine. *Id.* He is board certified by the American Board of Otolaryngology-Head and Neck Surgery with a sub-specialty certification in Otology, Neurology, and Skull Base Surgery. Ward Rep. at 1; Ward CV at 11. Dr. Ward has a clinical practice where he evaluates and treats patients with hearing and balance disorders, and has also published over 90 articles related to inner ear hearing and balance. Ward Rep. at 1; Ward CV at 2–8.

Dr. Ward summarized the relevant medical facts of the case and then briefly provided an overview of SSNHL. *See generally* Ward Rep. at 2–4. SSNHL is best understood, Dr. Ward proposed, as an inner ear disorder, and its diagnosis is based on symptoms of hearing loss corroborated by a specific kind of hearing test—a "pure tone audiometry."[6] *Id.* at 5. SSNHL can be accompanied by tinnitus and vertigo, but the "most frequently used audiometric criterion for the diagnosis is [evidence of] a decrease in hearing of at least 30 dB Hearing Level (HL) at three consecutive frequencies." *Id.* Dr. Ward agreed that Petitioner's sudden onset of symptoms in his right ear and subsequent hearing testing results were consistent with SSNHL. *Id.* at 5.

Dr. Ward opined that Dr. Monsell's proposed mechanism of vaccine causation was not scientifically or medically persuasive (although he largely deferred to Dr. Staats on questions of immunology). Ward Rep. at 6. He noted in particular that the "series of steps proposed by Dr. Monsell has not been demonstrated in the medical literature to be a cause of [SSNHL] in response to influenza vaccination. . ." Ward Rep. at 6. Moreover, the timing of Petitioner's hearing loss

[6] "Pure Tone Audiometry" is defined as "audiometry utilizing pure tones that are relatively free of noise and overtones." *Pure Tone Audiometry*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=59654&searchterm=pure+tone+audiometry (last visited May 31, 2024).

onset did not align well with Dr. Monsell's proposed theory for how a pathogenic immune response would unfold. *Id.* Petitioner had received his vaccination on October 27, 2018, but it was not until three weeks later that he developed ear fullness, and seven weeks before Petitioner's hearing loss was identified on pure tone audiometry testing. *Id.* This timeframe was too long for vaccine causation, in Dr. Ward's view. Indeed, some of the medical literature relied upon by Dr. Monsell suggesting a relationship between the flu vaccine and hearing loss demonstrates symptoms onset beginning within *days* of vaccination. *Id.*; C. Kolarov et al., *Bilateral Deafness Two Days Following Influenza Vaccination: A Case Report*, 15 Human Vaccines & Immunotherapeutics 107, 107 (2019), filed as Ex. 51 (ECF No. 34-10) (studying a 79-year-old female who developed acute bilateral sensorineural hearing loss two days after receipt of a seasonal influenza vaccination); A. Alsanosi, *Influenza A (H1N1): A Rare Cause of Deafness in Two Children*, 126 J Laryngol Otol. 1274, 1274 (2012), filed as Ex. 26 (ECF No. 32-5) (discussing two case reports of children who developed bilateral deafness within days after receipt of the influenza (H1N1) vaccination).

Dr. Ward also discussed in detail alternative explanations for Petitioner's hearing loss. He noted generally that in 90% of patients with SSNHL, a cause could only be deemed to have been idiopathic. Ward Rep. at 5, *citing* S. Chandrasekhar et al., *Clinical Practice Guideline: Sudden Hearing Loss (Update)*, 161 Otolaryngology–Head & neck Surgery S1, S3 (2019), filed as Ex. 40 (ECF No. 33-9) ("Chandrasekhar"). But the pure tone audiometry test could provide hints about possible explanations—particularly by distinguishing between middle ear disorders from "disorders of the inner ear in which there is impairment of the sensory structure or nerves." Ward Rep. at 5.

Here, Petitioner's first audiometry results, taken at a visit on December 17, 2018, indicated a partial impairment of the cochlea, auditory nerve, or higher aspects of central auditory perception or processing. Ward Rep. at 5; Chandrasekhar at S4; Ex. 4 at 10. Thereafter, Petitioner's hearing loss in his right ear progressed over time from moderate to a profound high-frequency sensorineural hearing loss (while he maintained good hearing at low frequencies). Ward Rep. at 5; Ex. 4 at 19. In addition, Petitioner had undergone a specialized MRI of the inner ear and brainstem with contrast, which did not identify the presence of any tumors of the hearing or balance nerves or inflammation within his inner ear. Ward Rep. at 5; Ex. 11 at 26.

Because the structure of the cochlea is highly organized in terms of how high- and low-frequency sounds are interpreted (high-frequency sounds are heard at the base while low-frequency sounds are heard toward the top of the cochlea), the cause of hearing loss would affect only a portion of the cochlea in the relevant ear. Ward. Rep. at 5. Thus, while Dr. Ward could not identify a specific, alternative inner-ear explanation for Petitioner's hearing loss, he noted that no other cause could be identified (lending some support to an idiopathic explanation).

At the same time, however, Dr. Ward took issue with Dr. Monsell's rejection of some possible other explanations for Petitioner's SSNHL. Regarding a potential asymptomatic viral infection, Dr. Ward emphasized (as Dr. Monsell had conceded) that SSNHL "is well documented in association with measles, mumps, and some herpetic infections," and that "[h]erpes simplex virus (HSV) has been associated with labyrinthitis, a disorder that causes hearing loss and vertigo symptoms [] as well as sudden sensorineural hearing loss." Ward Rep. at 7; *see also* S. Easki et al., *Auditory and Vestibular Defects Induced by Experimental labyrinthitis following Herpes Simplex Virus in Mice*, 131 Acta Oto-Laryngolgocia 684 (2011), filed as Ex. C-1 (ECF No. 43-14); A. Rabinstein et al., *Sudden Sensorineural Hearing Loss Associated with Herpes Simplex Virus Type 1 Infection*, 56 Neurology 571 (2001), filed as Ex. C-6 (ECF No. 43-19); Mckenna at 291. And in this case, there was medical record evidence documenting Petitioner's concern about exposure to HSV, leaving it a plausible counter-explanation. Ward Rep. at 7; Ex. 2 at 54.

Eustachian tube dysfunction also remained a reasonable alternative explanation, Dr. Ward opined. Treaters like Drs. Chen and Nugent had both included it in their differential diagnoses following their exam of Petitioner. Ward Rep. at 7; Ex. 8 at 6; Ex. 11 at 7. And eustachian tube dysfunction could still have constituted a contributing or potential casual factor in Petitioner's SSNHL, despite the inner vs. middle ear distinction and impact of each. Ward Rep. at 7. The sensation of ear fullness can be the result of eustachian tube dysfunction, even in the context of inner ear disorders such as SSNHL. *Id.* Here, Petitioner underwent a tympanometry on November 8, 2019, which showed negative pressure in both ears, and thus was consistent with dilatory or obstructive eustachian tube dysfunction. *Id.* at 7–8; Ex. 4 at 20; A. Schilder et al., *Eustachian Tube Dysfunction: Consensus Statement on Definition, Types, Clinical Presentation and Diagnosis*, 40 Clinical Otolaryngology 407 (2015), filed as Ex. C-7 (ECF No. 43-20). Moreover, Petitioner had a documented history of prior ear infections, chronic nasal allergies and gastro-esophageal reflux disease—all of which are risk factors for obstructive eustachian tube dysfunction. Ward Rep. at 8; J. Fischer et al., *Prevalence of Eustachian Tube Dysfunction in the US Elderly Population*, 163 Otolaryngology—Head and Neck Surgery 1169 (2020), filed as Ex. C-2 (ECF No. 43-15).

III. Procedural History

As noted above, this case was initiated in February 2021, approximately three years ago, and assigned to a different special master before being reassigned to me in August 2021. Thereafter, Respondent filed his Rule 4(c) Report contesting entitlement in November 2021. (ECF No. 24). The parties began the process of obtaining expert reports, with the final report from Dr. Monsell filed in June 2023. I proposed a briefing schedule for a ruling on the record, and the matter is ripe for resolution. *See* Petitioner's Brief, dated Sept. 28, 2023 (ECF No. 50) ("Br."); Respondent's Opposition, dated Nov. 17, 2023 (ECF No. 52) ("Opp."); Petitioner's Reply, dated Dec. 15, 2023 (ECF No. 53) ("Reply").

IV. Parties' Arguments

Petitioner

Petitioner generally argues he has met all three prongs of the test set by the Federal Circuit in *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005) for causation claims. Br. at 20. Regarding the first prong, he maintains that he has provided medical expert opinion and scientific literature demonstrating a sound and reliable mechanism articulating how the flu vaccine can cause SSNHL. *Id.* at 20, 29. Dr. Monsell adequately demonstrated, through cited medical literature, that inflammation in the small blood vessels critical to one's hearing are likely to play a significant role in the etiology of SSNHL. *Id.* at 21. In addition, Dr. Monsell has established that it is well known that the flu vaccine results in the influx of proinflammatory cytokines and acute phase proteins plus cytokines. *Id.* at 23.

Next, Petitioner contends that he has demonstrated a logical sequence of cause and effect between vaccination and his SSNHL Br. at 30. For example, Petitioner highlights several treater notes which he argues supports the alleged association. *Id.* at 31; *see also* Ex. 2 at 92 (documenting Petitioner's receipt of the flu shot several weeks before his SSNHL diagnosis and noting that the vaccine or acute URI could have play a contributing role); Ex. 8 at 6 (recording adverse reaction to vaccine). In addition, Dr. Monsell conducted a thorough review of the medical records and did not identify a more likely alternative cause, as noted in his detailed analysis of conditions/disorders that did not cause Petitioner's SSNHL. Br. at 32.

Lastly, Petitioner argues that the temporal relationship between his flu vaccination and the onset of his symptoms was medically appropriate. Br. at 35. Contemporaneous medical records consistently place the onset of his symptoms at approximately nineteen to twenty-five days post-vaccination. *Id.*; *see also* Ex. 11 at 6 (complaining of ear fullness and echoing sound in right ear for two weeks at November 29, 2018 visit); Ex. 4 at 7 (reporting right ear hearing problems beginning four weeks ago at December 17, 2018 ENT appointment). Petitioner further cites to the Baxter and Liuba articles to support a temporal relationship—noting that Baxter reported 167 cases of SSNHL beginning within one to twenty-eight days following receipt of the flu vaccine, and Liuba finding significant elevation in insults (*i.e.*, fibrinogen and C-reactive protein) at least two weeks post-vaccination. Br. at 37; Baxter at 84; Liuba at 393. Accordingly, a symptoms onset of approximately three weeks post-vaccination is not only consistent with Dr. Monsell's proposed mechanism, but falls within a medically acceptable timeframe. Br. at 38.

Respondent

Respondent contends the *Althen* prongs have not been satisfied. First, he maintains that Petitioner has failed to preponderantly establish that the flu vaccine can cause SSNHL. Opp. at 7. Petitioner's proposed theory is unreliable, as established by Drs. Staats and Ward. *Id.* at 8. In fact,

the cause of SSNHL is idiopathic in the majority of cases. *Id.*; Ward Rep. at 4. And even Dr. Monsell concurs that there is very limited evidence demonstrating what likely causes SSNHL. Opp. at 9.

Next, Petitioner has failed to produce reliable evidence that the flu vaccine "did cause" his SSNHL. Opp. at 15. There is insufficient record evidence demonstrating that Petitioner suffered any sort of elevated systemic immune response following his receipt of the flu vaccine—noting that Petitioner even reported feeling *well* the day of his vaccine, that the administration of the shot seemed standard and unremarkable, and that the following weeks were normal. *Id.* at 16; Ex. 14 at ¶ 2. Additionally, Respondent contends that Dr. Monsell failed to adequately address the significance of Petitioner's seasonal allergies or even the likelihood of an asymptomatic viral infection or eustachian tube dysfunction as causal. Opp. at 17. Petitioner had a demonstrated, extensive history of allergy and ear infections, and complained of having "a little bit of a cold or an allergy flare just a few weeks before" his right ear symptoms began." *Id.*; Ex. 4 at 7. Dr. Ward also observed that two of Petitioner's treating physicians diagnosed him with eustachian tube dysfunction following their examination, and thus it was improper for Dr. Monsell to dismiss these potential alternative causes. *Id.* at 18.

Finally, Respondent contends that Petitioner has not preponderantly established a medically acceptable temporal relationship. *Id.* He notes that Dr. Monsell agrees that Petitioner's symptoms onset began twenty-five days post-vaccination, bur argues that the timing of vaccination does not align with Petitioner's proposed theory for an immune response. *Id.* at 21. Dr. Monsell offered no medical literature supporting the induction of the APR as late as three weeks post-vaccination, but simply relies on Baxter (which identified more than 90 cases of SSNHL occurring within fourteen days, based on review of Kaiser Permanente Norther California electronic medical records database, including passive surveillance reporting of adverse events) as a medically acceptable timeframe for vaccine causation herein. *Id.* at 21–22. Respondent also criticizes Dr. Monsell's reliance on the IOM accepted timeframe for an immune-mediated response following vaccination up to forty-two days, as the IOM has not only provided any timeframe directly relevant to flu vaccine-induced SSNHL, but that instead this reference pertains to a distinguishable autoimmune disease. *Id.* at 22.

V. Applicable Legal Standards

A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly*, 592 F.3d at 1321; *Capizzano v. Sec'y of Health & Hum.*

Servs., 440 F.3d 1317, 1320 (Fed. Cir. 2006).[7] There is no Table claim for hearing loss associated with the flu vaccine, so in this matter Petitioner can only advance a causation-in-fact claim.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface*, 165 F.3d at 1352–53); *Pafford v. Sec'y of Health & Hum. Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen*, 418 F.3d at 1278: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury."

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu*, 569 F.3d at 1378–79 (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen*

[7] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. Appx. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras*, 121 Fed. Cl. at 245.

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory's scientific or medical *plausibility*. *See Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *see also LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) ("[h]owever, in the past we have made clear that simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof" (citing *Moberly*, 592 F.3d at 1322)); *Howard v. Sec'y of Health & Hum. Servs.*, No. 16-1592V, slip op. at *6 (Fed. Cl. Feb. 27, 2023) (confirming that "[t]he standard has been preponderance for nearly four decades"), *appeal docketed*, No. 2023-1816 (Fed. Cir. Apr. 28 2023). Otherwise, petitioners *always* have the ultimate burden of establishing their Vaccine Act claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their

suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for rev. den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Legal Standards Governing Factual Determinations*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [ ] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (determining that it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

As noted by the Federal Circuit, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his

contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Hum. Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Hum. Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, the Federal Circuit has also noted that there is no formal "presumption" that records are accurate or superior on their face to other forms of evidence. *Kirby v. Sec'y of Health & Hum. Servs.,* 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral or written testimony (provided in the form of an affidavit or declaration) may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs*.,

No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs*., 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). Under *Daubert*, the factors for analyzing the reliability of testimony are:

> (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

In the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings, like the district courts. Typically, *Daubert* factors are employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs*., 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not

been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs*., 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs*., No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. *Consideration of Medical Literature*

Both parties filed numerous items of medical and scientific literature in this case, but not all such items factor into the outcome of this decision. While I have reviewed all the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, No. 2015–5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.,* 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

E. *Standards for Ruling on the Record*

I am resolving Petitioner's claim on the filed record, and the parties have not challenged my determination to do so. Mot. at 2; Opp. at 2. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section

12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *Kreizenbeck v. Sec'y of Health & Hum. Servs*., 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also Hooker v. Sec'y of Health & Hum. Servs*., No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided case on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Hum. Servs*., 38 Fed. Cl. 397, 402–03 (1997) (determining that special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

I. Treatment of Hearing Loss Claims in the Vaccine Program

Program claimants have frequently argued that SSNHL was attributable to a vaccine. More often than not, such claims have not succeeded.[8] *See, e.g.*, *M.R. v. Sec'y of Health & Hum. Servs.*, No. 16-1024, 2023 WL 4936727 (Fed. Cl. Spec. Mstr. June 30, 2023) (evidence supported the conclusion that Petitioner's acoustic neuroma/vestibular schwannoma was the most likely cause of his SSNHL); *Kelly v. Sec'y of Health & Hum. Servs.,* No. 16-878V, 2021 WL 5276373, at *23 (Fed. Cl. Spec. Mstr. Oct. 18, 2021), *mot. for review den'd*, 2022 WL 2314746 (Fed. Cl. Apr. 13, 2022) (petitioner failed to establish any preexisting condition, leading to hearing loss, that was aggravated by the flu vaccine); *Inamdar v. Sec'y of Health & Hum. Servs.*, No. 15-1173V, 2019 WL 1160341, at *16 (Fed. Cl. Spec. Mstr. Feb. 8, 2019) (referencing multiple prior negative decisions involving SNHL or hearing loss); *Donica v. Sec'y of Health and Hum. Servs.*, No. 08-625V, 2010 WL 3735707, at *1, 10 (Fed. Cl. Spec. Mstr. Aug. 31, 2010) (flu vaccine not demonstrated to cause adult hearing loss); *Hopkins v. Sec'y of Health & Hum. Servs.*, Nos. 00-745V & 00-746V, 2007 WL 2454038, at *13 (Fed. Cl. Spec. Mstr. Aug. 10, 2007) (noting that the specific onset of hearing loss in child siblings after receipt of several vaccines could not be established). In most such cases, the *fact* of post-vaccination SSNHL was not disputed, but the claimants could not demonstrate the vaccine was causal.

[8] As noted above, I am not bound by the decisions of my colleagues—or even the Court's relevant decisions on review (except when stemming directly from a case I decided). *Boatmon*, 941 F.3d at 1358–59; *Hanlon*, 40 Fed. Cl. at 630. At the same time, special masters reasonably draw upon their overall, collective experience in resolving Vaccine Act claims. *Doe v. Sec'y of Health & Hum. Servs*., 76 Fed. Cl. 328, 338–39 (2007) ("[o]ne reason that proceedings are more expeditious in the hands of special masters is that the special masters have the expertise and experience to know the type of information that is most probative of a claim"). They would thus be remiss in ignoring prior cases presenting similar theories or factual circumstances, along with the reasoning employed in reaching such decisions.

I recently decided entitlement in *Kelly,* a case in which it was similarly alleged that the flu vaccine had caused SSNHL.[9] *Kelly*, 2021 WL 5276373, at *1. Although that petitioner maintained a significant aggravation claim, I found that my determination would have been the same even if the petitioner had alleged a causation-in-fact claim, and a discussion of all three *Althen* prongs was incorporated in that decision. *Id.* at *24. Petitioner proposed two mechanisms, a rapid Type I sensitivity reaction and an autoimmune response. *Id.* at *25. There was limited evidence to support this connection, however, and petitioner's contention that sudden hearing loss could be driven by an autoimmune process was inconsistent with the timeframe presented. *Id.* I also found that the petitioner's onset of less than two hours was too short to be deemed medically acceptable. *Id.* at *24.

In *Inamdar* (another case I decided), a petitioner argued that the flu vaccine had caused SSNHL, with onset the following day, based on two theories. *Inamdar,* 2019 WL1160341, at *5. First, the claimant argued that the vaccine "could cause the production of proinflammatory cytokines immediately upon vaccine administration." *Id.* But I determined that this argument relied too heavily on what was known about the wild virus rather than the vaccine. *Id.* at *6. The second theory was that specific components of the vaccine "were structurally homologous with ganglioside receptors on the neuronal myelin contained in the inner ear tissue, and that antibodies generated in response to the vaccine could also cross-react with the self-myelin, resulting in tissue damage." *Id.* I found, however, that this contention misapplied mechanisms relevant in other contexts. I also ruled that an alternative cause for the SSNHL (the fact that the claimant was receiving antibiotics at the time) existed, as well as that the short onset was not preponderantly defended. *Inamdar,* 2019 WL1160341, at *19. A too-short onset has been a notable obstacle to recovery in other cases. *See, e.g.*, *Donica,* 2010 WL 3735707, at *13 (two-hour post-vaccination onset of SNHL not demonstrated to be medically acceptable).

A different recent reasoned decision, by contrast, resulted in an entitlement decision favorable to the petitioner. *See Madigan*, 2021 WL 3046614, at *1, 4 (flu vaccine caused adult petitioner's SSNHL). The *Madigan* petitioner relied on a stress response theory and/or reactivation of a latent HSV-1 infection (although the latter did not play into the case's resolution), utilizing an expert different from Dr. Monsell. *Madigan,* 2021 WL 3046614, at *9–10, 17. As observed in *Madigan,* the stress response theory had not been presented in prior adverse decisions like *Inamdar* or *Kelly.* The theory as presented therein placed special emphasis on an immune pathway's stimulation by vaccination, causing inflammation elsewhere in the body sufficient to impact the ear. *Id.* at *9, 12. Indeed, it was deemed a "good candidate for explaining the clinical characteristics of idiopathic sudden hearing loss," and accepted as reasonable by Respondent's expert (although he did not also believe the flu vaccine could trigger it). *Id.* at *13.

[9] *M.R.* is an even more-recent SSNHL case, but it turned primarily on whether an alternative to vaccination was the cause of the hearing loss—and in this case there is no comparable evidence of an obvious explanation, thus reducing the guidance value of that determination.

The special master in *Madigan* further accepted the petitioner's argument, supplemented by literature, that vaccination can increase circulating cytokine levels that could travel to the ear and cause harm, rejecting Respondent's expert's invocation of Baxter on the grounds that (a) its findings with respect to a lack of vaccine association were less robust for longer time intervals, and (b) its onset determinations had not (in the estimation of Petitioner's expert) been sufficiently confirmed. *Madigan,* 2021 WL 3046614, at *15–17. Also notable in *Madigan* was the fact that vaccine causation had treater support, and other lab work findings were consistent with the stress response theory. *Id.* at *18–19.

Madigan unquestionably offers positive parallels for Petitioner herein. But I do not find the causation theory therein offered, or the decision embracing it, to be compelling, reliable, or persuasive. I have on many occasions considered theories asserting a vaccine-caused stimulation of the innate (and hence immediate) immune process led to injury, but have repeatedly deemed such theories wanting, absent evidence connecting the process (no matter how scientifically plausible it might be) with additional proof sufficient to render it "more likely than not" that the immune processes outlined could be rendered pathogenic by introduction of a vaccine. Otherwise, such a theory only attempts to transmute the expected reaction to a vaccine into pathology. *Dean v. Sec'y of Health & Hum. Servs.*, No. 13-808V, 2017 WL 2926605, at *17 (Fed. Cl. June 9, 2017). What was accepted in *Madigan* reads the same as what I have so often confronted, but rejected, in prior cases.

More significantly, however, the onset in *Madigan* was far sooner, measured against vaccination, than the onset at issue in this case. 2021 WL 3046614, at *20. That petitioner received a flu vaccine on December 9, 2021, and was first seen for complaints regarding ringing in his left ear *four days later*. *Id.* Here, Petitioner's first documented complaint of a sensation of fullness in his right ear occurred more than three weeks after vaccination. Ex. 11 at 2–16 (discussing sensation of echoing ear fulling at visit with Dr. Chen).

II. Petitioner Has Not Carried his Causation Burden of Proof[10]

A. *Althen* Prong Three

The resolution of this case primarily turns on the third *Althen* prong. Even if it is assumed that Dr. Monsell's theory (which admittedly varies somewhat from what has been presented in otherwise-relevant prior cases) was preponderantly established, the timing of Petitioner's onset was temporally too remote from vaccination to find a medically-acceptable association.

Here, the record preponderantly supports the conclusion that Petitioner's SSNHL onset occurred over three weeks post-vaccination. Ex. 14 at ¶ 2; Ex. 11 at 2–16. While in at least one

[10] I address the prongs in order of their significance to my determination.

contemporaneous record Petitioner appears to have supported a slightly shorter onset (19 days), and in another reports a general, mid-November onset, the most precise onset date is found in the record when Petitioner first sought medical care for his hearing loss, and it is reasonably given the most weight. Petitioner's expert also seems to have embraced it. Monsell First Rep. at 2, 27.

This timeframe is not consistent with Petitioner's causation theory, which contemplates a fairly sudden and acute inflammatory occurrence impacting the middle ear and attributable to the initial, innate immune response to vaccination. Monsell First Rep. at 19–24. Nor can it be defended by reference to other items of literature Petitioner has offered. Liuba, for example, primarily saw only a heighted, vaccine-associated risk of inflammatory damage in a shorter timeframe (two weeks), even if it allowed for some possible risk thereafter. Liuba at 398.

Baxter has even less probative value. Ignoring the fact that its headline findings are *fully unsupportive* of a causal relationship, Baxter only identified *some* patients who had developed SSNHL within any timeframe relevant herein—and in so doing emphasized that the identified cases could not be deemed statistically significant proof of a vaccine-associated risk. Baxter at 84. It certainly does not support a four-week onset, as Petitioner's briefing contends, based solely on the fact that cases on hearing loss *occurred* in that longer post-vaccination timeframe. This kind of *post hoc ergo propter hoc* reasoning is unconvincing, and does not suggest the timeframe is medically reasonable. *Galindo v. Sec'y of Health & Hum. Servs.*, No. 16-203V, 2019 WL 2419552, at *20 (Fed. Cl. Spec. Mstr. May 14, 2019) (citing *U.S. Steel Group v. United States*, 96 F.3d 1352, 1358 (Fed. Cir. 1996). And I do not give significant weight to attempts to borrow timeframes for autoimmune processes opined to occur post-vaccination but resulting in non-comparable injuries, such as in the context of Guillain-Barré syndrome.

It is simply more likely, if Petitioner's APR theory had validity, that an individual experiencing the processes Dr. Monsell proposes as causal of sudden hearing loss would also experience those processes acutely—more *suddenly* after vaccination. This is consistent with other causal theories that have been accepted (albeit uncommonly), such as in *Madigan*. A three-week abrupt onset, with no evidence of any intervening issues that could support the conclusion that some aberrant process was underway, is therefore unpersuasive, as Respondent's experts convincingly argued.

B. *Althen* Prong One

As noted above, I have on several prior occasions considered arguments that the flu vaccine can cause SSNHL, but found the theories unreliable and/or unpersuasive. Nothing offered in this case suggests these determinations were in error, even though the theory offered herein varies slightly.

First, the proposition that hearing loss might be immune-mediated in some contexts does not mean a vaccine's *general* stimulation of the immune system is likely pathogenic in this specific way. This kind of argument rests on a faulty logic common in Program cases: if vaccines stimulate the immune system, *and* there is a possible immune-mediated pathogenic explanation for an injury, then the *expected* immune process can also turn pathogenic in susceptible individuals. *See, e.g.*, *Olson v. Sec'y of Health & Human Servs.*, No. 13-439V, 2017 WL 3624085, at *20 (Fed. Cl. Spec. Mstr. July 14, 2017) (deeming it speculative to purport that cytokine upregulation due to a vaccine "would be robust enough, and occur for long enough, to be pathogenic generally, let alone to cause" the complained-of injury), *mot. for review den'd*, 135 Fed. Cl. 670 (2017), *aff'd*, 758 F. App'x 919 (Fed. Cir. 2018). In order to elevate such a theory above mere plausibility, however, a petitioner must connect it with evidence that suggests that at least the analogs for a vaccine's antigenic components might be capable of triggering such a process; the fact that vaccines generally impact the immune system (and cause localized inflammation or stimulate cytokines that can initiate inflammation elsewhere in the body) is only the *starting point* for a successful theory.

The same is true here, despite the distinguishable context of ear inflammation. At bottom, Petitioner's theory as articulated by Dr. Monsell proposes that the initial, innate response to vaccination (as it is not contended that the flu vaccine caused the production of antibodies that would, via an autoimmune mechanism, cross-react with self-structures resulting in ear damage) would cause SSNHL. But I do not find this contention persuasive or sufficiently corroborated to deem the vaccine causal. As Drs. Staats and Ward collectively established, it is not likely that the limited systemic inflammatory effect of an unadjuvanted flu vaccine would result in a cascading, pathologic process specific to the inner ear.

The evidence offered for the theory was ultimately inadequate. Dr. Monsell offered several studies specific to other kinds of injuries, for example. *See, e.g.*, Liuba at 393 (focused on cardiovascular risk in temporal wake of "acute inflammatory disorder"). Items of literature more specific to the ear, like Adams, did not establish that SNHL is *only* or predominantly mediated by immune processes, did not evaluate the extent to which a viral infection could cause this kind of immune interference (let alone vaccination), and were forthright in acknowledging their speculative or hypothetical aspects. However specifically reliable in the narrow context of their findings, their hypotheses have not been shown to have been corroborated with any additional studies sufficient to support Petitioner's theory.

In addition, there is evidence in this case *directly undercutting* a vaccine-SNHL association—a large-scale epidemiologic study, Baxter, that reached statistically-reliable results, and observing that a flu-vaccinated population's incidence of hearing loss was not higher than an unvaccinated group. Baxter at 83. I have in other cases noted the probative value of Baxter, regardless of the fact that it cannot ever fully rebut the possibility of a rare instance of vaccine causation. *M.R.*, 2023 WL 4936727, at *32. And this class of evidence is not embargoed from

consideration merely because claimants are never compelled to offer it. *See Perekotiy v. Sec'y of Health & Hum. Servs.*, No. 16-997V, 2020 WL 12904810, at *13 (Fed. Cl. Spec. Mstr. Apr. 20, 2020), *mot. for review den'd*, No. 16-997V, 2020 WL 5887548 (Fed. Cl. 2020) (citing *Andreu*, 569 F.3d at 1378–79).

Admittedly, Petitioner can reference evidence of treater support for a causal relationship. Br. at 10; Ex. 8 at 4–6. That evidence has relevance to both the first and second *Althen* prongs (although it is more commonly invoked in connection with the second prong). But special masters are never bound to take treater views at face value. And here, the limited treater support for the vaccine being causal of SSNHL is not especially reliable. Dr. Nugent, for example**,** not only was not a specialist in either ear issues or neurology, but saw Petitioner more than a year after onset—and appears to have presumed a causal relationship between vaccination and hearing loss based on *Petitioner's* statements. A treater somewhat closer-in-time to Petitioner's receipt of the flu vaccine, Dr. Lough, noted the vaccination—along with Petitioner's having suffered an acute URI several weeks prior to the onset of his symptoms—as a potential contributing factor, but did not elaborate on its putative association with SSNHL. Ex. 2 at 92 (1/7/2019 follow-up visit at Renown Health). Such treater views thus warrant limited weight under the circumstances.

C. *Althen* Prong Two

Although the case is properly dismissed based on my findings with respect to the first two causation prongs, I note that the second, "did cause" prong was also unmet.[11] Record evidence does not establish that Petitioner ever experienced any adverse inflammatory response to the vaccination—whether at the time of receipt or in the weeks leading to his hearing loss. But this should likely have occurred if Dr. Monsell's theory (APR-associated immune reactions triggered by vaccination building up to an inner ear impact) explained how Petitioner's SSNHL was actually occurring. I give this evidence more weight than the few instances where treaters notated the *possibility* of the flu vaccine as contributory to Petitioner's SSNHL. Ex. 2 at 92; Ex. 8 at 6. To find otherwise—to say that because Petitioner's onset occurred "after" vaccination, a "logical sequence of cause and effect" was proven—would be to read out of analysis entirely the second prong, subsuming it within the first, as if once a claimant's theory is established, the mere fact of post-vaccination injury is enough to carry the day.

CONCLUSION

Preponderant evidence does not support Petitioner's causation theory, nor (even if I had accepted it) is it likely his hearing loss occurred in a medically acceptable timeframe, measured from vaccination. Accordingly, he is not entitled to compensation.

[11] In so concluding, I give limited weight to Dr. Monsell's arguments about why other possible causal explanations for Petitioner's SSNHL were invalid or unlikely—even though he devoted large portions of his reports to addressing them, and in so doing made a number of reasonable and convincing points.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court **SHALL ENTER JUDGMENT** in accordance with the terms of this Decision.[12]

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[12] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.